K051659

JUL 13 2005

510(k) Summary

Submitter:	SIGNUS Medizintechnik GmbH Brentanostrasse 9 D-63755 Alzenau Germany
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Date Prepared:	June 17, 2004
Trade Name:	SEMIAL™
Classification Name and No:	21 CFR 888.3060
Product Code:	MQP
Predicate Device	Curved PEEK Tetris™ cleared under K041888 on 10-Aug-2004.
Device Description:	The SEMIAL™ Spinal implant is a hollow, semi-cylindrical form, slightly curved frame with tapered edges. The upper and lower aspects of the implant are open and the walls feature spikes which assist in the positive anchorage and seating of the implant between the superior and inferior vertebral bodies. The frame is forged from PEEK (PEEK-OPTIMA™ LT1), which is radiolucent, and incorporates small Titanium alloy (TiAl6V4) marker pins so the device can be located within the body. The marker pins meet ASTM F-136 and ISO 5832/3. The SEMIAL™ Spinal Implant is available in a variety of sizes ranging in height from 9 mm to 49 mm with a enrolling diameter of either 43mm or 38mm and either a 2.5° or a 5.2° angle. A list of SEMIAL™ sizes and model numbers maybe found in **Appendix A**. The provision of varying heights, together with a wedge shaped option, to allow better lordosis control, enables the surgeon to choose the size suited to the individual pathology and anatomical condition. The SEMIAL™ may be implanted individually.
Intended Use:	The SEMIAL™ Spinal Implant is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. The SEMIAL™ is intended to be implanted singularly. The supplemental internal fixation systems that may be used with the SEMIAL™ Spinal Implant are the same as the Curved PEEK Tetris Spinal Implant and include, but are not limited to, DePuy AcroMed

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	titanium plate or rod systems (Kaneda SR, University Plate, M2, ISOLA, VSP, Moss, TiMX, and Profile).
Statement of Technological Comparison	The subject device have the following similarities: • The same indication for use; • The same operating principle; • The same basic design; • The same materials; • Implanted using the same surgical techniques and equipment; • Used in conjunction with the same types of supplemental internal fixation systems; • The same manufacturing environment; • The same sterilization process; and • The same packaging configurations. In summary, the SEMIAL™, as described in this submission is, in the opinion of Signus GmbH, substantially equivalent to the predicate device.
Conclusion:	The SEMIAL™ as modified in this submission, is substantially equivalent to the predicate device, Curved PEEK TETRIS™ cleared under K041888. This conclusion is based upon the similarities of the devices in terms of functional design, indication for use, principles of operation, materials, and performance characteristics.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SIGNUS Medizintechnik GmbH
C/o Ms. Tracy L. Gray
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4050 Olson Memorial Hwy
Suite 350
Minneapolis, Minnesota 55422

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Re: K051659
Trade/Device Name: SEMIAL™ Spinal Implant
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: June 17, 2005
Received: June 24, 2005

Dear Ms. Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Page

510(k) Number (if known): K051659

Device Name: SEMIAL™ Spinal Implant

Indications for Use:

The SEMIAL™ Spinal Implant is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. The SEMIAL™ is intended to be implanted singularly.

The internal fixation systems that may be used include, but are not limited to, DePuy AcroMed titanium plate or rod systems (Kaneda SR, University Plate, M2, ISOLA, VSP, Moss, TiMX, and Profile.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X Or Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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